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Schiza, Eirini C.; Kyprianou, Theodoros C.; Petkov, Nicolai; Schizas, Christos N.

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Proposal for an eHealth Based Ecosystem Serving National Healthcare

Eirini C. Schiza, *Member, IEEE*, Theodoros C. Kyprianou, Nicolai Petkov, and Christos N. Schizas, *Life Senior Member, IEEE*

***Abstract*—The European Union (EU)'s keen concern about citizens' health and well-being advancement has been expressed at all levels. It has been understood that at present, these can only be achieved through coordinated actions at the individual member states' level based on EU directives, as well as through promoting and funding R&D and expanding the use of eHealth technologies. Despite the diversities and particularities among member states, common values such as universal access to good quality healthcare, equity, and solidarity have been widely accepted across EU. That demanded the adoption of policies and follow directives, which streamlined actions to bridge healthcare gaps, and facilitate cross-border healthcare. This paper articulates a framework for deriving a national healthcare system, based on interoperable Electronic Health Record (EHR) with safeguarding healthcare quality, enabling quadruple helix (Public, Academia, Industry, NGOs) driven R&D and guided by a patient-centered approach. A methodology to develop an integrated EHR at National level is proposed as a prerequisite for eHealth and put into perspective. Recommendations are given for the steps needed, from the managerial, legal, technical, and financial concerns in developing an open access, patient-centered national healthcare system based on the context and constraints of a country. The example of a small country to apply the proposed methodology is demonstrated. Stakeholders, including citizens, healthcare professionals, academia, and the industry are mobilized, enabled, and incentivized for implementing the methodology. Experiences are aspired to be offered as lessons learned for other countries to adapt on their environment.**

***Index Terms*—Electronic Health Record (EHR), eHealth, Interoperability, Patient-Centered Healthcare, Public Health, National Healthcare.**

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E. C. Schiza and N. Petkov are with the Department of Intelligent Systems Group, Johann Bernoulli Institute for Mathematics and Computer Science, University of Groningen, 9712 CP Groningen, Netherlands (e-mail: ischiza@cs.ucy.ac.cy; n.petkov@rug.nl).

T. C. Kyprianou is with the Department of Intensive Care Medicine, Nicosia General Hospital, Nicosia 2029, Cyprus (e-mail: tkyprian@gmail.com).

C. N. Schizas is with the Department of Computer Science, University of Cyprus, Nicosia 2109, Cyprus (e-mail: schizas@ucy.ac.cy).

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I. Introduction

IN THIS paper, we address the main barriers to overcome in building an integrated, interoperable National Healthcare System covering the whole population, as well as allowing access to visiting and migrating population. 'Interoperable' simply means that the EHR of a citizen is remotely accessible by healthcare providers; it is readable and understandable by all health providers, thus facilitating the best possible medical service to the citizens. In a national healthcare ecosystem, we will define the environment in which healthcare coverage is provided to the whole population and its visitors, without any restriction or prejudice. The term ecosystem is used metaphorically for emphasizing that a national healthcare system is a complex network of interconnected systems that interact with each other and with conflicting interests. The healthcare "system" can be better understood as an ecosystem of interconnected stakeholders, each one charged with a mission to improve the quality of care while lowering its cost. To ensure patient's safety and quality care while realizing savings, these stakeholders are building new relationships often outside the four walls of the hospital. Few of the new relationships, such as health provider-payer that are taking shape, are explained in detail in this paper [1].

In the following sections, we present, analyze and discuss the main topics related to this challenge and introduce solutions with road marks guided by the related EU directives and other international initiatives. We suggest how a country, like Cyprus, can build its own eHealth ecosystem based on EU principles and directives. We give historical background with the main landmarks of the EU efforts and we concentrate on the current state-of-the-art and the EU research initiatives in which Cyprus is participating. By utilizing the technological solutions offered by the EU-funded initiatives and claim active role, every EU country can follow analogous paths for realizing their healthcare ecosystems. In principle, every country's healthcare system should serve its purpose within their legal, technical and financial frameworks and at the same time remain EU directives' compliant without diverting from the citizen-centered objective.

The concept of healthcare for all, at least for Cyprus, extends back to ancient times, and this fact was used as leverage for touching people's self-esteem and lower possible resistance to change. For instance, the recognition that environmental factors can have an impact on human health can be traced back to as far as the physician Hippocrates (460–370 B.C.) [2]. This perception, also known as all-embracing healthcare, evidenced

by the *Idalion Bronze Tablet* discovered in Cyprus [3], [4]. It refers to the reached agreement between King Stasikypros and the citizens of Idalion on one hand, and doctor Onasilos and his brothers on the other. The doctor agreed on an all-embracing scheme to treat those injured during the war around 470 B.C., when the Persians and the Phoenicians of Kition attempted to conquer Idalion. The King and the city agreed to compensate Onasilos and his brothers with a fixed amount expressed in silver or plots of land. In modern days, this notion is expressed as national healthcare system, and the fact that the agreement was taken jointly by the King and the citizens, demonstrates the Greek democratic ideals on the political system of the kingdom and the existed solidarity regarding financial compensation. Furthermore, the care and concern felt by the 'city-state' authorities towards the citizens, provides evidence for the existence of the most ancient system of social welfare known to us that employed citizen centered idealism [4].

The EU with Directive 2011/24/EU [5] gave a definition of patient-centered approach that applies the social welfare principle based on the value that patients are owners of their own medical records. At that point, EHR (Electronic Health Record) was introduced as the central ingredient for achieving patient-centered approach, an approach that has long routs especially when it comes to solidarity driven principles.

Individual efforts have been made by EU countries for updating existing or developing new national health systems. The most recently completed and well-commended example is the one in Estonia where the EHR uniformly covers the whole country and virtually registers all citizens' medical history from birth to death and based on state-developed IT infrastructure. It was launched in December 2008, and since January 2009 all healthcare providers have been obliged to incorporate an agreed number of standardized medical documents, electronic information notes and electronic medical documents to it [6]. Other countries such as Austria and Sweden started their efforts two decades ago and their efforts continue with excellent functionality at country level. Their diffusion with other EU countries is slow because of lag of standards across Europe [7]–[9]. Individual eHealth Strategies Country Reports and further information about eHealth initiatives in Europe have been prepared and funded by the European Commission, DG Information Society and Media, ICT for Health Unit in 2009 and it is available online [10].

The purpose for writing this article was motivated by the claim that an *all-included* pan-European health system can only be achieved through the individual nations' implementations following the relevant EU directives rather than implementing a general system and forcing it to the member states. Some of the abovementioned example can be studied by another country as exaples to be followed, but in no way one should expect that they can be transplanted as they are in another country. This claim embodies a very fundamental principle of EU that takes into consideration the diversities, particularities, maturity and readiness of member states in following revolutionary reforms. Such reforms concerning healthcare have been discussed and dreamed for at least a decade in Europe with the motto, "citizen-centered healthcare". The first reading of this motto produced three

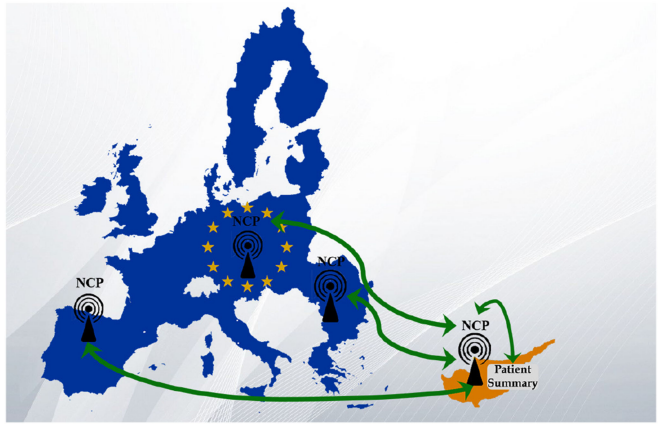

Fig. 1. Example of the role of a National Contact Point (NCP). Each NCP is responsible for patient summary interchange.

fundamental pillars: Catholic, Mutual guarantee, and Access to all. The member states were asked to accept these principles and EU undertook the responsibility to facilitate them with technical knowhow, knowledge sharing and experiences gained in more advanced member states in order to be able to leapfrog, minimize the societal and technological gaps and set their strategy for building their local health ecosystems integrated into a pan European and beyond.

In this paper, we also aim to explain the importance of studying the country circumstances to achieve the EU goals of cross-border healthcare, as simplified in Fig. 1 with the introduction of National Contact Points (NCPs). In Section II, 'Foundations of a National eHealth System' we explain Interoperability and stress its important role in eHealth. In Section III, 'Method', we justify the proposed dynamic methodology. In Sections IV, V, VI and VII, the patient-centered approach, the Technical, Financial, and Legal Frameworks are respectively discussed, and finally, in Section VIII, we discuss the proposed actions and a roadmap for achieving an eHealth based Ecosystem.

II. Foundations of a National eHealth System

EHR is defined as a structured collection of constantly updated healthcare data associated with a citizen throughout one's life. EHR management systems enable storage and retrieval of patient's data and facilitate physicians and other healthcare providers to provide safer and more effective care through embedded clinical decision support and other intelligent systems. EHR can also support public health and biomedical national and international research. Additionally, better management, improved care coordination and chronic diseases management, cross-border medical care, handling of interoperability issues, reduction of medical errors and delays, reduced operational costs, personalized prescription, and patient enactment and participation are expected [11], [12].

Interoperability, an important feature of modern EHR is defined as the ability to reach the record from different vendors, and to interact with other computers across local or wide-area networks regardless of their physical architecture and operating

systems. It is feasible through hardware and software components that conform to open standards such as those used for internet.

The essence of healthcare systems nowadays is to provide efficient, results-driven, cost-effective services, addressing the real needs and preferences of citizens/patients and the society. Patient-centeredness was considered a radical approach not so long ago, and the EHR is the cornerstone and precondition of patient-centered eHealth [13].

Patient-centered approach mainly relies on listening to, informing and involving patients in their care in such a way that care is provided in a respectful and responsive to the individual patient's preferences, needs and values [14]. In practice, the patient becomes the owner of their EHR, granting permission per need to healthcare providers.

Designing and building an EHR system, as an operational and functional entity, is possible for IT professionals (analysts, designers and developers) in close collaboration with health professionals as proper functioning and exploitation of the EHR benefits, requires semantic interoperability of medical information. This level of interoperability is absolutely needed for dissimilar EHR systems, business related information systems, medical devices, mobile technologies, and other systems to improve wellness, as well as the quality, safety, cost-effectiveness, and access to healthcare delivery [15]. It also requires considerable effort and input from management services and end users. Excellent efforts were made by international vendors and organizations like WHO for establishing universally accepted tools and methods to be used for building national eHealth strategies using common communication protocols and standards [16], [17].

Lag of interoperability is the key obstacle on all current solutions offered and it is a crucial functionality that an EHR management system should offer to healthcare. The benefits of interoperability extend to all actors [18]: *healthcare professionals* – for supporting decision-making procedures via advanced and contemporary status of patient information and evidence-based clinical guidelines; *patients* – delivery of care at the point of need, more reliable and personalized care, integrated care including treatment abroad; *users* - lower implementation and integration costs for interoperable systems; *healthcare businesses* - the use of a common eHealth EU Interoperability Framework facilitates the expansion of a digital single market for healthcare thus creating competition which in turn reduces the development cost.

The new era of cross-border healthcare in EU is now regulated by EU directives which address also privacy and confidentiality, personal data, and data protection issues are highly relevant when deliberating EHR [19]. These evolvements made patients increasingly alert regarding their benefits and claimed the right to choose their health providers including those beyond their national borders. Telemedicine for instance is evolving because of the rapid development of technology and because of the cross-border healthcare since there is collaboration between healthcare professionals across borders. This is believed to be the single most important revolution in healthcare since the advent of modern medicine, vaccines, or

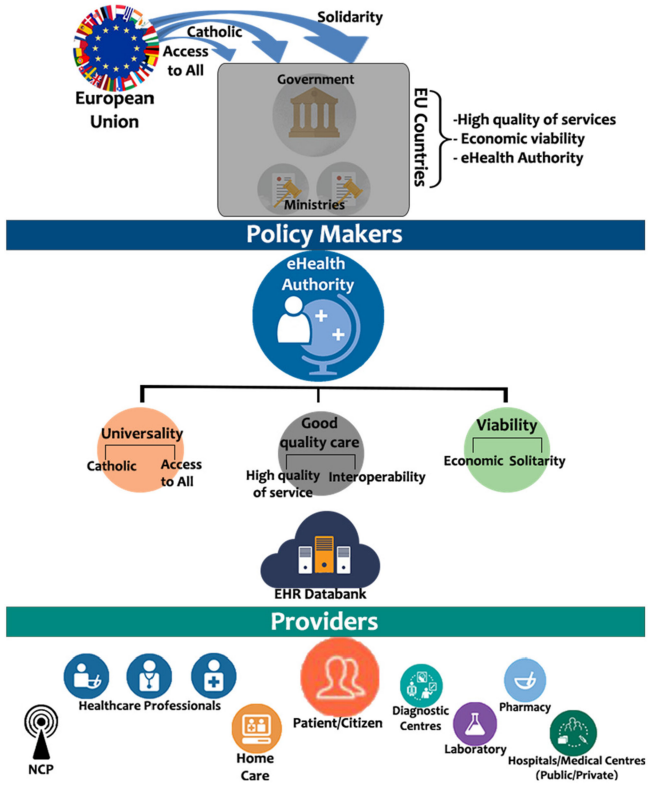

Fig. 2. National eHealth Authority is the Regulator of the ecosystem, being the setting up of the country NCP for health for cross-border healthcare, the licensing, regulating and controlling the operation of institutions for storing EHRs in interoperable databanks.

even public health measures like sanitation and clean water [20]. eHealth and *patient-centered* approach mainly through the implementation of national and eventually pan-European EHR systems, is demonstrated by the recently announced Horizon 2020 work program titled 'Health, Demographic Change and Wellbeing' [21].

A central aim for the design and implementation of a global national healthcare system is to secure financial viability and sustainability. This will prevent underestimating the cost and it will minimize the risk for inevitably increasing the citizen's financial contribution for preventing the collapse of the system. Financial viability can be sustained by introducing another pillar to the system being High Quality of Services in association with efficiency and reforming public hospitals into cost centers. The gained status will allow them to become competitive and operate in a free economy environment along with the private hospitals and other private medical centers.

Instituting and regulating a *National eHealth Authority (NeHA)*: The appointment of such a body by the highest authority being the council of ministers, will create a regulating body with legal powers for enforcing standards in medical, social, and financial services for securing interoperability at local and EU levels as seen in Fig. 2. *NeHA* will form the next pillar of the ecosystem.

Biomedical research could also be greatly benefited by integrating it into the national technical and legal system for

Fig. 3. eHealth Ecosystem Pillars.

sharing patients' data an option (from the patient and the healthcare professional point of view) that would enable collection of anonymized data (biosignals, diagnoses, notes, lab results, images, videos, etc.) and central/distributed storage paired with analytics toolbox [22]. The development of such infrastructure would ideally involve stakeholders from the quadruple helix (Public, Academia, Industry, NGOs) [23].

The ultimate scope is to progress into a new healthcare ecosystem securely supported by six pillars, as illustrated in Fig. 3, serving the citizens at national and pan-European levels and bridging private and public sectors.

In the process of building on the pillars mentioned above, the most challenging obstacles are those related to organizational, process and infrastructure aspects since these are deeply rooted in the culture of societies and the way people are used to do things and pass these to newer generations. In Cyprus those challenges have been handled systematically from primary school to the university level through specialized seminars and courses in University curricula [24]. Similar efforts are taken for educating health professional through seminars.

III. Method

To reach an optimal result in designing and implementing a state-of-the-art, interoperable, affordable and sustainable national eHealth ecosystem to support healthcare reform, our team had to find a fine balance between the 'ideal' and the 'realistic', applicable to this country. In that respect, many variables have been taken into consideration: a) the country's and stakeholders' maturity level for technological, legal and social reforms described in Section VII; b) International technological standards recommended by EU through directives, decisions and reports described in depth in Section V; c) Emerging technologies and solutions developed by R&D activities of the local scientific community in Section V – paragraphs C&D; d) Adoption of a patient-centered approach necessary to support interoperability, described in Section IV; e) The legal framework necessary to allow for universal coverage, interoperability and adoption of technological standards described in Section VII, and f) The cost of individual tenders pertaining to different parts of the ecosystem, the cost partition between public and private sectors, the available budget for initial investment and running expenses and opportunities for external funding (i.e., EU structural and cohesion funds) described in Section VI.

The research methodology used for addressing the aforementioned challenges was a classic structured systems analysis and design method (SSADM). A chief systems analyst familiar with the system's environment and the roles of the main players of the system was appointed to head an ad-hoc *NeHA*. Their first task was to estimate the Capability Maturity level of the system for minimizing risks and optimizing the competitiveness of the system's life cycle [25], which in this case was estimated to be Level 4. This methodology has been chosen as our group has developed competency in using it [26], [27]. The systems group (ad-hoc *NeHA*) has recruited when deemed necessary, stakeholders' representatives and users community members i.e., public health & financial policy makers, health professionals from the private and public sectors, patients' organizations, IT experts, public and private insurance organizations, legal and IPRs/Data protection experts etc. Those players have been interviewed and become actively involved in the development of the aimed eHealth ecosystem. Before interviewing, executive presentations on eHealth concepts and its benefits were organized and public discussions were initiated and facilitated. At least twelve such presentations were organized and followed by structured interviews. Overall thirty interviews were analyzed, and user requirements and opinions were surfaced. The findings were processed and presented to relevant groups by the senior analyst and structured or unstructured feedback was received. Policy and decision makers were challenged to take actions accordingly.

The legal framework was revisited several times as twenty-four relevant laws of the country were studied and the related articles had to be taken into consideration, crossed checked with relevant groups, the legal service and the commissioner for data protection for legal compliance and verification (laws and regulations from the national electronic repository: http://www.cylaw.org). A dedicated law regulating eHealth through a national committee for e-Health has been drafted and submitted for parliamentary approval as described in detail in Section VII.

Eventually, the pillars for a national health ecosystem have been formed, priorities have been set, user and technical requirements have been finalized and a solid plan has been put forward. The national strategy for implementing an eHealth ecosystem accompanied by a roadmap and an action plan received a presidential endorsement and support. Problems arose from interoperability i.e., legal, ethical, technical, and financial were dealt with accordingly, as suggested in the relevant sections here below in the paper.

Based on the methodology described above, the steps described below were followed:

Step 1: Built a model and a roadmap of the eHealth ecosystem and rendered it part of the country's presidential strategy;
Step 2: Agreed on the minimum technological functionalities of the system;
Step 3: Designed the financial model of the system and secured necessary commitments;

Step 4: Revisited national legislation and accommodated all functionalities, duties, responsibilities, and rights of all stakeholders into the system; and

Step 5: Established by law the *National eHealth Authority* to undertake the non-trivial task of regulating, coordinating and supervising the implementation of the eHealth ecosystem and the necessary reforms.

IV. The Patient-Centered Approach

The principal aim is to design and build a complete EHR system for replacing the standard paper medical records. Thus, it is aimed to improve clinical decision making by storing and retrieving medical data in various forms. When a patient is under the care of more than one doctor, tracking one's history, including allergies, blood type, current medications, chronic illnesses, past procedures, and all the relevant data that a patient summary may include, can be problematic when relying on paper folders [13], [17]. The remote access of EHR allows multiple care providers, regardless of location, to simultaneously access a patient's record from any computer connected to the Internet. The EHR features contribute to lower costs, significant time savings, resulting to better quality and greater efficiency [28].

The central player in healthcare has been the doctor, who has long been described, as 'doctor knows best'. While the doctor may indeed have the knowledge and responsibility for care, that does not mean one knows best. In the new paradigm dictated by the *patient-centered* approach, the information is no longer flowing from the top. Data and information are not knowledge, and for the latter, the doctor will continue to be its source. Moreover, the intimacy at the heart of the best doctor-patient relationship, where a patient can reveal their secrets and worst fears or experiences, the physician's touch to promote confidence and healing cannot be compromised and should never be lost. The aim is to strengthen this relationship by supporting the health professional with a sophisticated EHR intelligent environment and by providing continuous education in health informatics.

EHR is used by citizens for maintaining and managing their own health data, even by enriching them through innovative mobile applications, which serve as sensors for monitoring health indices and the course/early phases of a disease [29]. Patients, being the central focus of healthcare delivery, gain benefit by avoiding duplicate testing, lab procedures, imaging examinations because all test results are kept in one historical file, which is also remotely accessible. Coordination and remote access among health providers can lead to better and accurate diagnoses, better overall care especially to chronic patients [28]. Healthcare providers and patients who share electronic access to health information can collaborate in intelligent decision-making. Patient participation is especially important in managing and treating chronic conditions such as asthma, diabetes, and obesity [30].

Patient-centered approach is giving the patient another role, instead of being the problem or part of it, one is made part of the solution. This elucidates why the integrated EHR is the cornerstone for attaining this through a unique account for every citizen created automatically at birth with its first medical data belonging to the fetus and inherited from the mothers EHR at the earliest ∼9 months before birth [26], [31]. From that moment onwards, each time a citizen visits a healthcare center, her EHR will be updated accordingly. Access to the medical data is permitted only after the authorization and consent of the owner and in line with the legislation for privacy and confidentiality. Data kept in the EHR can be used for clinical tests and for research purposes only after the prior consent of the owner/citizen. This approach is promoting the motto 'aiming for health to minimize illnesses from birth till death'. This approach is excellently described and illustrated in practice in a recently published book titled *The Patient Will See You Now*, which must be read by every health professional, citizen, and government official [32].

Health Affairs editor-in-chief Susan Dentzer stated, "It is well established now that one can in fact improve the quality of healthcare and reduce the costs at the same time." Quality of care improvement and simultaneous cost reduction principle can only be achieved if the citizen becomes the central actor, a principle that lead to the term *patient-centered care*. One of the most important rudiments contributed by the patient-centered approach is the quality assurance to the General Integrated National Health System [33]. Physicians practicing *patient-centered care*, by improving the quality of the doctor-patient relationship improve their patients' clinical outcome and satisfaction, while decreasing hospitalizations and referrals. This approach replaces the current classical *physician-centered* system with one that revolves around the patient. Effective care is mainly defined by or in consultation with patients rather than by physician-dependent tools or standards [34].

V. Technical Framework

The technical framework used for implementing the system, incorporating the existing legacy systems, and designing the additional new subsystems needed is addressed below:

A. EHR Summary Standards

One important technical issue that needs to be addressed is the construction and implementation of the EHR in an interoperable environment that can process diverse data. Every member must follow EU guidelines and standards. Regarding EHR, the deliverables of the epSOS project was adopted and turned into Directive 2011/24/EU '*minimum/non-exhaustive patient summary dataset*' applicable both to the unexpected, as well as the expected healthcare contact [5], [17]. The relevant guidelines were incorporated in the legislation as a standardized set of basic health data for the patient (e.g., name, birth date, gender, etc.), medical summary consisting of the most important clinical patient data (e.g., allergies, current medical problems, medical implants, or major surgical procedures during the last six months), list of the current medication including all prescribed medication that the patient is taking and information about the Patient Summary itself. The steps followed were the identification and inclusion of the different specialties, such as cardiology, gynecology, pediatric etc., as seen in Fig. 4. A complete interoperable EHR for the citizen is enabled in combination with an eHealth Cloud infrastructure. The EHR was further enhanced

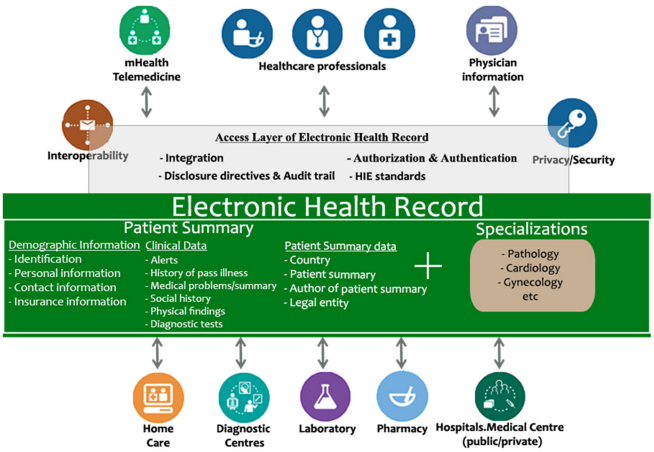

Fig 4. Structure and functionality of the Electronic Health Record. Layer 1 – Patient summary with specializations, Layer 2 – interoperability privacy and security, Layer 3 – Health providers and medical centers.

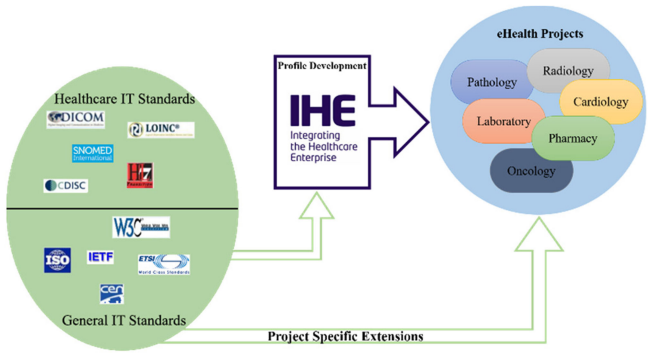

Fig. 5. Interoperability Standards and Medical System.

by giving the option to the citizen to enter in a separate section of the EHR any data that is considered important for the medical professional to see when the citizen issues such a request.

B. Standardization for Storage Retrieval and Communication

In healthcare, standards provide a common language and set of expectations that enable communication between systems. Such standards in healthcare are HL7, ISO, CEN, ICD10, SNOMED and other in a wide variety of ways [35]. Harmonizing different information systems requires data translation and mapping, as well as document and messaging standards. Integrating the Healthcare Enterprise (IHE) is an initiative that brings together users and developers of medical information systems to advance data integration. Adopting IHE, technical interoperability is secured and gives value by coordinating the use of established standards for the specific clinical needs [36]. The lack of cooperation by many hospital systems fail to satisfy everyone's effort to automate processes, create and review medical reports [37]. The adoption of IHE standards automated these processes and brought about a very efficient medical workflow.

The goal of the IHE Technical Framework is to define the interactions among system components so that the roles of the actors are not assigned to specific industry products, such as hospital information or radiology information systems. The vendors of the different system components suggest how the actors' roles are implemented [37]. Overall, the IHE technical framework helped to build a market for standards-based integration by giving incentives, education and tools for both providers and purchasers.

IHE is not a standard; it supports the use of existing standards in an integrated manner. It is simply an implementation framework creating interoperability between medical systems. IHE provides templates that can be used as standardized tools to build starting points for optimizing workflows in a uniform way, as demonstrated in Fig. 5, adopted from 'http://wiki.ihe.net/index.php'.

Guidelines and the steps followed for our implementation methodology are briefly stated here: *Problem Identification phase* - Clinicians and IT experts were asked to identify problems when accessing data, problems with the administration infrastructure, and problems with their clinical workflow. Then stakeholders select the most suitable standards for each identified integration need. *Integration Profile Specification phase* - Those standards are documented in the IHE technical framework. Vendors implement the selected integration profiles and test their systems with software tools and at a face-to-face Connectathon [38], a cross-vendor, live, supervised and structured testing event where industry leaders test implementations of IHE Profiles to advance health IT interoperability. The IHE Connectathons take place annually in various countries across the world to advance health IT and patient safety. Lastly, vendors publish IHE Integration Statements to document the integration profiles supported by their systems – which is the Integration Statement and RFPs phase.

The most recent profiles that were developed by the IHE regarding EHR services used the Fast Healthcare Interoperability Resources (FHIR) standard from the HL7 organization for exchanging healthcare information electronically [39]. FHIR solutions or Resources are a set of modular components, which can be easily assembled into working systems for solving real world clinical and administrative problems in a very efficient manner. FHIR solutions are explicitly suitable for EHR-based data sharing and server communication in large institutional healthcare providers. FHIR defines a simple framework for extending and adapting existing resources and this could solve many interoperability problems that all anticipate in their way [40].

The eHealth Lab of the University of Cyprus developed with success in collaboration with IHE under the FI-STAR project the IHE profiles below. FI-STAR aims to build a vertical community for creating a sustainable ecosystem for all user groups in the global healthcare and adjacent markets [41].

- IHE PDQ: Patient Demographics Query; where, Patient Demographics Query provides ways for multiple distributed applications to query a patient information server for a list of patients, based on user-defined search criteria, and retrieves a patient's demographic information directly into the application.

- IHE XDS.b: Cross-Enterprise Document Sharing; where, Cross-Enterprise Document Sharing (XDS.b) IHE Integration Profile facilitates the registration, distribution, and access across health enterprises the EHR.

Cross-Enterprise Document Sharing is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprises, ranging from a private physician to a clinic of an acute care in-patient facility.

The European Commission Decision (EU) 2015/1302 of July 2015 has decided the 27 IHE profiles describing the different layers of interoperability with a view to find interoperability solutions for exchanging or sharing medical data [42]. In Fig. 5, one can see the different IHE profiles establishing the cross-border communication between the provider and the receiver and also for exchanging medical information between systems. IHE Integration Profiles organize sets of IHE actors and transactions for addressing the specific needs for care of patients. These profiles offer a convenient way for vendors and users to communicate in a standard way the functionality that is defined in the IHE Technical Framework without having to provide all the details of the IHE actors and their transactions. They describe clinical information and workflow needs and specify the actors and transactions required to address them. Thus, IHE profiles can be used for the system development and are in compliance with the EC decisions.

C. Technical Solutions and Tools Developed

As stated earlier, three open source software libraries, namely the EHR SE, epSOS SE and PACS SE, were developed by the eHealth Lab of the University of Cyprus [43] in the context of the FI-STAR platform and were designed to facilitate the deployment of innovative applications and value-added services in the healthcare sector [44]. Targeting towards the enrichment of the FI-STAR framework for use in the healthcare domain, the EHR-EN software library addresses the objectives to build: i) the EHR specific enabler (EHR-EN); ii) the patient summary specific enabler based on the 'European Patients Smart Open Services' (epSOS) project (epSOS-EN), and iii) the Picture Archiving and Communications System (PACS) specific enabler based on the dcm4che open source software (PACS-EN). These three FI-STAR platform enablers developed and used by our eHealth lab can facilitate the deployment of similar innovative applications and value added services in the healthcare sector and are readily available in public domain [41].

As a pilot study, a full EHR application has been developed by the eHealth Lab of the University of Cyprus for the needs of the EU project eENERCA dealing with rare congenital conditions that require lifelong follow up and treatment [45], [38]. The proposed eRegistry serves as an epidemiological tool to improve the management of patient services and ultimately improve patient care [19]. For this project the following modalities were created: Demographics, Diagnosis, and Clinical Data. Patients and healthcare providers benefit from this eRegistry, since they were provided with valuable sources of information on their disease. eRegistries for rare anemias can further benefit research due to their design and capacity to follow a broad group of patients for long periods. These registries assume a critical role in improving comprehension of rare anemias by creating guidelines for disease treatment and management and providing information to assist the development of new treatments. This system laid the foundation for a consensus, and evidence-based disease management system, and as demonstrated in a recent publication, eHealth-funded initiatives supported by EU can benefit through applied research by citizens in need and the medical profession [27].

The experiences gained above were very valuable as it taught us how a national eHealth ecosystem can be gradually built once the technical framework and the tools become available to the expected team of professionals. Lessons learned can speed up the efforts of other EU countries in securing interoperability and functionality.

D. eHealth Cloud

It is stated that eHealth aims at "cost-effective and secure use of ICT in support of health and health-related fields, including healthcare services, health surveillance, health education, knowledge and research" [46]. Cloud computing is a facility or service that eliminates the need of an organization to maintain in-house special and expensive hardware, network infrastructures, and costly technical professionals for supporting and operating in-house ICT systems. The Cloud offers diverse IT solutions and resource time-sharing as on-demand services for different organizational needs, and it enhances resources utilization and service delivery [47]. A special type of Cloud, an eHealth Cloud that can solve some of the current limitations faced by healthcare ICT solutions was proposed [48]. An eHealth Cloud can be physically situated in a country and regulated by local legislation, thus satisfying to an extent, security and confidentiality concerns, which are some of the main obstacles brought forward when it comes to adopting ICT solutions that require interoperability, high volume and remote access to medical data.

The apparent scalability, flexibility and availability of cloud services and the low cost associated, contributed to the rapid adoption among enterprises or health related agencies in recent years. Patient-centered healthcare encourages citizens to be involved in their own healthcare activities, and the cloud-based platform provides a technical solution and a valuable option. When data become available in the cloud, it is subject to security preconditions and can be processed by remote services or distributed automatically to all relevant health providers. As stated by one of the authors of this paper: "Around one third of the studies show that the security and privacy gaps of healthcare data in the cloud could be solved by access control encryption schemes and security protection techniques" [49]. This suggests that it would be possible to switch current eHealth services to improved eHealth Cloud-based services. This was considered as the most suitable for our case to serve as central host of all the EHRs of the citizens and those visiting the country and would like to have readily available their EHR while visiting Cyprus. The eHealth Law provided an entire framework for such a specialized cloud and operated under the control of the National eHealth Authority.

Evidently, an eHealth Cloud platform, with all technologies incorporated, offers an excellent opportunity to the healthcare industry for addressing challenges such as patient care, quality and safety, healthcare costs, ICT and access costs, backup and security, and collaboration and knowledge sharing among healthcare professionals at any geographical area. An overall outcome will be the *high quality services at the lowest cost for healthcare.* The general advantages are summarized as follows: i) Reduction of the cost of owning and maintaining hardware, software, and people-ware of ICT systems; ii) Integration and exchange of medical records across multiple experts locally and worldwide; iii) Enhancement of diagnosis, support medical research activities, and simplification of administrative operations; and iv) Improved availability, scalability and flexibility of the health information system.

Several issues and challenges have been addressed before the eHealth Cloud was considered as a good alternative approach for this healthcare service. The major concern was the security and privacy issues, which were adequately addressed. Financial and legal concerns are addressed in the following sections. To date, the available security and privacy measures are at an acceptable level of confidence. The inclusion of strong security measures when the owner is not available can be handled by deciding beforehand and in agreement with the owner by signing a properly prepared consent form [49].

VI. Financial Framework

The present Cyprus healthcare system comprises two parallel sub-systems, being the public and the private. These systems operate separately and independently resulting in inefficiencies, low communication and overall coordination of healthcare. The funding of this system is mainly covered directly from the pockets of the citizens, implying a lack of justice and solidarity within the healthcare sector. Therefore, if the public and private sectors continue to operate separately, it would not hold back further wastage of resources, overlaps in services, and lack of quality of service [50], [51].

The public sector is owned and operated by the Ministry of health. They are responsible for ensuring access to health services for all beneficiaries and were exclusively financed by the taxpayers. The Ministry of health is however responsible for the regulation, planning, licensing, and quality control for the entire health sector, realities which make the role of the Ministry highly debatable. The Ministry placed patients into three categories based on income, chronic illnesses, and number of children, consisting of people who receive treatment free of charge, those who pay reduced fees and those who pay fully [50]. Not even the full charge represents the real cost due to the lack of proper cost estimation system in place. As a result in most cases, the cost was underestimated and the taxpayer is called to cover the deficits.

The private sector is mostly financed by out-of-pocket payments and this covered about 55% of the total healthcare budget; and from this, approximately 87% is covered by out-of-pocket being about 2.5 times higher than the average figure among all EU countries. In the Netherlands, for example, the corresponding figures are 18% and 30% while the average out-of-pocket is below the EU average. Private health services in Cyprus are provided by privately owned hospitals, polyclinics and clinics, independent practitioners, diagnostic centers, and pharmacies, which are regulated, licensed, and inspected by the Ministry of health [52].

Health services in the public sector are covered by five district hospitals and one pediatric/gynecological hospital, three small rural hospitals and 38 health centers. The Ministry covers nearly 80% of the population which is entitled for free healthcare in the public sector. The rest of the population is receiving treatment privately, and a small proportion receives treatment in public hospitals at a cost.

A study of the healthcare expenses in Cyprus over the last twenty years has shown an exponential growth averaged to about 8%, while the GDP growth remained around 4%. As a result, the system was going bankrupt unless money was pumped in by the taxpayer or the quality of service was compromised. Alternatively, an efficient and effective National Health Insurance System (NHIS) was proposed on the bases of eHealth and citizen-centered principles, which seemed as the only realistic way for defeating the crisis.

Just for the history, in June 2012, the Cyprus Government applied for financial assistance from the Eurogroup and the IMF. As precondition to this, the participating institutions forced Cyprus embark on an economic adjustment program aimed at restoring the health of the financial sector, continuing the ongoing process of fiscal consolidation and to implement structural reforms that support competitiveness, balanced and sustainable growth [53]. One of the actions taken for restoring this was the gradual implementation of a National Health System for providing comprehensive medical care to the entire population, achieving universality in coverage, good quality of care, equity, solidarity, and long term financial sustainability. The proposed system was an insurance-based system, which has been designed to address the current challenge, distortions and deadlocks in the healthcare sector characterized by:

1. Universal coverage meaning all Cypriot citizens/EU citizens and other legally living in Cyprus to become beneficiaries of this system.
2. Comprehensive benefits package for covering a broad spectrum of healthcare services such as primary care, clinical laboratory tests, emergency care etc.
3. Equal treatment where all beneficiaries have the same rights in respect of the provision of healthcare services.
4. Free choice to the citizen for healthcare provider.
5. Solidarity where each citizen will contribute according to their income level.

Currently, the top priority of the Government and Ministry of health is to continue reforming healthcare and upgrade public healthcare centers to autonomous, ensure healthcare is patient-centered, reliable and accessible. Next step, Health Insurance Organization (HIO) which was set up under the Law N.89(I)/2001 as a public legal entity to support its mission, which is the implementation of the proposed National Health Insurance System (NHIS) operating initially as a closed system [54]. The HIO which is partly controlled by the government is the strategic

buyer of health services by all public and private providers on an equal basis. The insurance fund of HIO is generated by the contributions of the social partners being the employees, the employers, and the State.

The free market began generating competition forcing the public hospitals to undergo radical operational and organizational changes. Another novelty brought by the NHIS was the reorganization of the Primary Care sector by having the citizens to choose their family doctor including the pediatrician, thus relieving crowding in public hospitals. The family doctors are compensated per capita and not per visit, and the patient only uses the secondary or tertiary care through referral from the family doctor. Similarly, prescriptions for pharmacies and laboratory test can only be issued by the appropriate personnel and compensated directly by the HIO. These reforms are generating a fully financially accountable NHIS, whose greatest success will be eventually the savings in healthcare spending and its transformation to a positive-sum game, thus generating added value and extra benefits to the citizen at a lower cost.

The above summary of the state of affairs and the necessary reformation was made by adopting the eHealth approach in line with an interoperable, national coverage, cross-border, and citizen centered healthcare system. A preposition for an eHealth ecosystem on these lines is presented in the discussion section below. Its functionality and operability is gradually implemented and tested by the EU funded initiative CEF-TC-eHealth CY-IA-0095 (26922256) -*Deployment of Generic Gross Border eHealth Services* in which the Ministry of health of Cyprus and the eHealth lab of the University of Cyprus are participating. In this initiative another 15 EU countries are participating. Parallel to this, the initiative CEF-TC-EESSI-CY-IA-0016 (27574468) -*Cyprus Electronic Exchange of Social Security Information*, funded by EU is in progress since March of 2018, for supporting the full functionality of the country's healthcare ecosystem to operate at EU level.

VII. Legal Framework

A successful legal framework for healthcare management should address and regulate the following mainly conflicting domains: i) EHR-definition and content; ii) EHR-ownership and access; iii) catholic-applied to all citizens and to all healthcare providers; iv) solidarity-mutual guarantee; v) economic viability-sustainability and cost effectiveness; vi) high quality-services in medical care; vii) autonomy-in the framework of operation and running of the system; viii) interoperability at national and cross-border levels, and ix) the establishment and the operation of EHR databanks. These domains were studied by the systems design team and the relevant national legislation was revisited.

In a constantly changing technological environment, a significant impediment to the successful implementation of eHealth is not only the technological complexity and the challenges presented, but also the lack of adequate and necessary legislative framework to cover this effort [55]. In achieving an effective legal framework, each country needs to study its national legislation and take into consideration the EU legal framework and directives. An important issue when implementing a new EHR system is the system's compliance with the law regarding the rights of patients. Each country has its own legal system; however, all member states should comply with the guidelines, standards and legislative framework set by the EU. For example, before the accession of Cyprus to the EU a series of laws were inherited from EU, including those relating to patients' rights and the protection of the data generated and stored. Therefore, a study on the capability level of the national legislation on these issues was performed. It also took into consideration the differences and idiosyncrasies of the locals, and derived recommendations for the amendments to be introduced as new legislations or amend accordingly existing laws. This safeguarded a smooth transition into the new order with less rejection probability.

The EHR although it is based on an evolving concept oriented approach that provides improved healthcare quality, the patient should not deny the 'right' of the medical professional to be informed when needed and to safeguard this. For this, it was necessary to establish an appropriate legislative framework so that all the necessary procedures and actions to be taken conformed to the law as it applied locally and at EU level. Such considerations include electronic processing and collection of personal data of the citizen, and the movement both within their state borders and cross-border.

The British Medical Association mentions that, "the physician must maintain secrecy on all he knows". In this general principle, however, there are five exceptions, releasing the doctor of confidentiality: when the patient gives her consent, when it serves the interests of the patients, when the doctor's duty to society prevails, and for research purposes as approved by the Ethics Committee for Clinical Research and the information required for legal procedures [47].

New announcements of the European Parliament, such as the *eHealth Action Plan*, emphasizes how ICT can be used to provide better quality healthcare services throughout the Community. The crucial aim of this action was the creation of a 'Pan-European eHealth' for recording practical measures to be applied in various fields. The eventual goal of the program is that by the end of the decade, eHealth to bind the habits of health professionals toward a citizen centered thinking. It was, however, necessary to regulate this kind of thinking by legislation in order for the application to become effective.

Data banks are used for storing medical data. The storage of such data in a central location raises new questions about the protection of personal data, which do not arise when data is on paper. For example, who can have access to these data? Who can generate information from? How safe is the personal data? Evidently, the protection of personal data by appropriate legislation is absolutely important. Intellectual property or copyright or exclusive rights of the copyright of a work should be granted by law and be valid for a certain time and forbid others to use the work without the consent of the author. The copyright is an arbitrary right of each author and applies without the need to make application to one institution or work to be recognized by a service [56]. The Government is responsible to support the requirements by introducing appropriate legislation when needed.

The EHR systems are subject to the risk of unauthorized processing of personal health data of the patient, thus, new safeguards to ensure the protection and privacy of personal medical data are required. The establishment and operation of EHR systems must comply with the principles of protection of personal data set by the EU Directive 95/46/EC [57]. When it comes to health, this directive varies and many times prohibitive principles formulated can affect the smooth operation of an organization. Maintaining confidentiality for patient records on paper is not enough to secure the privacy of patient medical data when files are converted into electronic form. So far in the existing legislation there is no rule of conduct on neither eHealth nor clear principles defining accountability in case of technical problems of information systems related to healthcare. Therefore, the adjustment of hospital organization to technological change requires changes in the existing regulatory framework.

In many cases, a transitional grace period is given to avoid undesirable shocks at the early stages of implementation for safeguarding a smooth transition. Through the study of relevant legislation that exists worldwide, it became clear that the legislation in Cyprus was at a primitive stage. The legal framework required radical reform and necessary political will for promoting the integration and the widespread use of EHR and eHealth in general. The success of EHR to the greatest extent depends on the human factor and to a lesser extent to legislation. Acceptance is a matter of mindset and culture and necessary measures through education and awareness were taken as part of the whole strategy [24]. It was necessary to bring together the stakeholders. The study in question was based on an analysis of the existing infrastructure so that the necessary measures were adopted before any implementation. The legislative measures to be decided, was the result of an overall analysis that put into the equation social, political, organizational and technological issues.

It would be worth for a country to follow the steps that Cyprus took recently for revisiting the relevant laws for accommodating the pillars of eHealth stated earlier. Initially, a general health sector reform strategy has to be decided at the highest political level and supported by three main pillars: 1) eHealth, 2) Reform and homogenize all public and private hospitals and health centers, and 3) Promote research and collaboration with academia with all healthcare providers. The second pillar included the reform of the legislation in accordance with the existing Cyprus law for cross-border (L. 149(I)/2013) which led to the introduction of a new law explicitly for regulating eHealth in Cyprus. A team of experts studied the relevant EU Directives 95/46/EC and 2011/24/EU, and Executive Directive 2012/52/EU as well as twenty-four national laws relevant to healthcare, such as the law for pharmaceuticals, operation of clinics, medical profession practicing, establishment and protection of patients' rights, etc. and prepared the eHealth law in harmony with the cross-border care law. The new law was presented and discussed, negotiated and agreed with all interested bodies, including the Cyprus Medical Association, the Federation of Patients Associations and Friends of Cyprus – Member of EPF (European Patients Forum), the Health Insurance Organization, the Cyprus Pharmaceutical Association, and all healthcare providers. The agreed bill was submitted to the Parliament for approval. The approval was secured a priori as it was already negotiated and agreed with all involved.

The main expectancies of the bill were:

1. The EC Regulation No 883/2004 on the coordination of social security systems is incorporated in the bill, thus making all the citizens of Cyprus beneficiaries for healthcare and as a consequence become beneficiaries at EU level. It was observed that until the approval of the bill, many Cypriots were not beneficiaries at EU level.
2. Citizens of other countries are covered by the Regulation 859/2003/EC or by the Regulation 1231/2010/EC, thus become beneficiaries in Cyprus.
3. The Council of ministers appoints the *NeHA* which acts as the regulator of the associated affairs, such as the setting up of the NCP for health for the country for cross-border healthcare.
4. The definition of the content of the EHR, being the *patient summary*, the *extended summary*, and the *citizen's optional space* for adding relevant data.
5. Regulation of the use of the EHR, its ownership, its content, the users, and their rights and obligations.
6. The obligation of healthcare providers, and operators of other related services of being able to access, retrieve, download, and upload the parts of EHR that are relevant to the medical examination being performed.
7. The promotion and dissemination of modern forms of electronic data exchange, education and professional training.

The national eHealth system and the supervision of the healthcare providers is becoming a reality upon gradual implementation of the above points of the law. The *NeHA* being an independent and autonomous entity contributes a lot in the harmonization of the medical care centers nationwide. The new era in the running of public hospitals brings in independent quality experts. Furthermore the introduction and enforcement of the law for administrative and financial autonomy makes all the public hospitals and medical centers competitive, operating in a free economy environment along with the private hospitals and medical centers.

When a country reaches such a maturity level, the new *eHealth Law*, which incorporates all the gained experiences, harmonizes the operation of eHealth at national level.

VIII. Discussion and Conclusion

This paper purposely has some extra theoretical background and prepositions for the reader to consider and judge if applicable in the problem under consideration. The suggested methodology and approach for building an eHealth ecosystem for serving national healthcare is country dependent and subject to many parameters within the sub-system's environment. The paper however, is not limited to a theoretical framework but it took all the steps forward and developed a solution for Cyprus which is progressing evolving and growing. This system was evaluated and tested with commercial standards before put into practice. From the legal point of view certain changes were

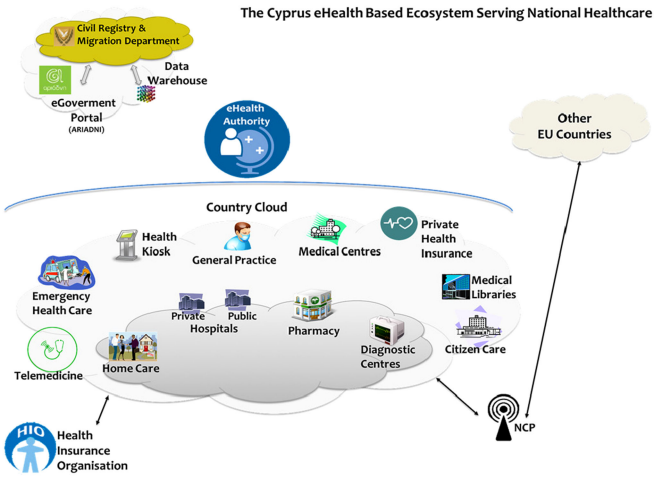

Fig. 6. The Proposed Cyprus National eHealth Ecosystem – having eHealth authority regulate eHealth facilities including health insurances, hospitals, medical centers, NCP, etc. NCP communication with origin country and the requested EU country.

suggested and the existing legislation was revisited appropriately and new *eHealth law* was introduced. These reforms entertained any justifiable concerns regarding legal, ethical, and cultural issues. The changes come within and not imposed by the outside and as a result made their acceptance a natural reformation. The last section analyses the financial framework which based on the fundamental pillars catholic (all-included), and solidarity compromised to a NHIS initially operating as a closed system with a unique health insurance provider, the HIO, which is controlled by the government and the main stakeholders.

The proposed eHealth Ecosystem for Cyprus is illustrated in Fig. 6. The most important parts being the Central Citizen Data Warehouse, which uniquely links every citizen to the Central eGovernment Portal, the country Cloud integrated EHR system which is regulated by the *NeHA* thus satisfying interoperability and citizen-owned EHR, confidentiality, and security; and the providers appropriately linked to the HIO for financial issues and the NCP for health for cross-border health care. It would not be difficult to accommodate into this system any non-Cypriot citizen who chooses to obtain a user account and store one's data on the Cyprus Cloud at an annual fee bases. This facility offered to non-Cypriots will not make them entitled for health insurance cover but it will simply facilitate them with an interoperable EHR. Countries like Cyprus who receive annually more than three times their population in tourists and business travelers should not underestimate the potential benefits to be gained from such services. Travelers will demand such services in the near future and countries should act proactively by offering them. Similarly, health tourism can be promoted and give Cyprus a competitive advantage if the service is open for non-permanent citizens.

As a conclusion, it can be said that paving the way towards EU principles by following the relevant directives for a fully interoperable healthcare system is not a trivial task. It takes structured efforts at social, political and scientific levels to incorporate and build on modern eHealth IT technologies, to mobilize, enable and incentivize stakeholders, including citizens, decision makers, healthcare professionals, academia and the industry. This structured methodology as described, inevitably modified based on local circumstances without abandoning basic principles and its ethos, is considered as absolutely necessary to overcome internal resistance to change and system's inertia. The case of Cyprus aspires, this way, to offer its collective experience as lessons learned for other EU countries which are puzzled as to how to proceed towards the same direction for healthcare reform and remain in line with EU directives and values for the citizen.

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